

REMARKS

The application has been carefully reviewed in light of the Office action, and amended as necessary to more clearly and particularly describe the subject matter that Applicant regards as the invention.

Claims 1-25 are currently pending in the present application. Claims 1 and 4 have been amended to correct translation and/or typographical errors, and claim 3 has been amended to better meet the formal requirements of U.S. practice. Claims 21 and 22 have been amended to remove their reference to claim 1 to better meet the formal requirements of U.S. practice. Reconsideration of the present application is hereby requested.

In the Office action, the Examiner maintained his election/ restriction requirement requiring the Applicant to elect a single invention from Groups I and II to which the claims shall be restricted, wherein Group I corresponds to claims 1-20, drawn to a method of preparing bone cement, and Group II corresponds to claims 21-25, drawn to apparatus for preparing bone cement. Applicant submits that this requirement is contrary to established U.S. patent law and is in direct conflict with 37 CFR §1.475, which states (with emphasis added):

b) An international or a national stage application containing claims to different categories of invention ***will be considered to have unity of invention*** if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

With regard to categories of claims, it is noted that claims 1-19 of the present application are directed to a method of preparing bone cement, claim 20 is directed to bone cement prepared by the method and claims 21-25 are directed to apparatus for carrying out the method. Thus, the claims of the present application clearly and unmistakably fall within category 5 of 37 CFR §1.475 and *therefore have unity of invention*. Accordingly, Applicant hereby requests the Examiner to reconsider and withdraw his restriction/election requirement so as to obviate the need for Applicant to petition the Commissioner to review the requirement.

In the Office action, the Examiner noted that specification should avoid references to specific claim numbers. In accordance with the Examiner's observation, Applicant has amended the first paragraph on page 1 of the specification to remove the references to specific claims.

The Examiner rejected claim 3 under 35 U.S.C. §112, second paragraph, as being indefinite for using the phrase "preferably contained within said particles". In response, Applicant has amended claim 3 to delete the phrase. Applicant submits that claim 3 (and the other claims) meet the requirements of 35 U.S.C. §112, second paragraph.

The Examiner has rejected claim 20 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,051,482 to Tepic. In rejecting claim 20, the Examiner stated that "There is no reason to believe that the location of the vacuum source in any

way affects the bone cement product". Applicant submits that the use of an initial internal vacuum, such as in the Tepic patent, leads to a heterogeneous bone cement mixture, which increases residual monomer and air inclusion and decreases tensile strength. In contrast, the use of an external vacuum in accordance with the method of claim 1, produces a homogenous bone cement mixture, which decreases residual monomer and air inclusion and increases tensile strength. Accordingly, Applicant submits that the bone cement mixture of claim 20 is homogenous, whereas the bone cement mixture of the Tepic patent is heterogeneous. Thus, the bone cement mixture of the Tepic patent fails to anticipate the bone cement mixture of claim 20 of the present invention.

The Examiner has rejected claims 1-11 and 17 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,051,482 to Tepic in view of WO 97/18031 to Jonsson. For at least the reasons set forth below, Applicant traverses this rejection.

The Tepic patent discloses a method and apparatus for preparing a bone cement mixture, wherein a syringe 11 with an evacuated inflexible chamber 4 is filled with polymethylmethacrylate (PMMA) beads. An adapter 13 containing an ampule 12 filled with liquid methylmethacrylate (MMA) monomer is inserted into the syringe and the MMA is sucked into the chamber 4 by the action of the internal vacuum therein.

The WO 97/18031 reference also discloses a method and apparatus for preparing a bone cement mixture. In the WO 97/18031 reference, a mixing vessel 2 has an interior 2a with an agitator 6 disposed therein. The agitator 6 includes an agitator disc 6a movably mounted to a tubular agitator rod 6b. The interior 2a contains a volume of bone cement component B and is connected to a vacuum source through a filter 8.

As shown in Fig. 1, a substantial gap is formed between the top of the volume of bone component B and a top wall forming interior 2a. A container 9 is provided with an ampoule 11 containing bone cement component B. When it is desired to produce the bone cement mixture, the container 9 is connected to the mixing vessel 2 and the ampoule 11 is broken. The bone cement component A moves downwardly through the agitator rod 6b under suction from the vacuum source. The bone cement component A enters the bottom of interior 2a through a gap 23 that is connected to an end 6e of the agitator rod 6b. As set forth on page 6, lines 9-12 of the WO 97/18031 reference, the gap 23 "behaves as a passage for percolating an air/liquid mixture upwardly through holes 6h in the agitator disk 6a, so that air bubbles cause liquid A to thoroughly mix with the powder component B". Once bone cement components A and B are mixed, the container 9 is removed and replaced with a tightening rod 19. The agitator rod 6b is then physically moved up and down to physically mix the components. The mixture is then discharged through a top end 6c of the agitator rod 6b by axially displacing a bottom 4 of the mixing vessel 2.

In rejecting claims 1-11 and 17, the Examiner concedes that "While the powder container is pre-evacuated, the act of connect a vacuum source to an outlet port is of the container is not explicitly disclosed." The Examiner, however, finds that it "would have been obvious to one of ordinary skill in the art to have connect a vacuum source to the outlet port of Tepic ('482) because WO 97/18031 explains that such a connection provides the dual benefits of '[r]apid and effective feeding' and 'safe handling of the gases that are environmentally harmful and injurious to human health'.

Applicant submits that contrary to the Examiner's assertion, there is no motivation to combine the WO 97/18031 reference with the Tepic patent. The objective of the Tepic patent is to avoid air inclusions, such as are produced by mechanical stirring. As set forth in column 1, lines 21-23, the Tepic patent states that "mechanical stirring, even under vacuum, produces air inclusions which weaken the finally hardened cement mass". The WO 97/18031 reference, however, advocates the inclusion of air bubbles. As set forth above, the apparatus of the WO 97/18031 reference is designed **"for percolating an air/liquid mixture upwardly** through holes 6h in the agitator disk 6a, so that air bubbles cause liquid A to thoroughly mix with the powder component B". Such percolation causes heterogeneous flooding of the powder component B, thereby requiring mechanical mixing of the powder after the powder has been flooded. Thus, the the WO 97/18031 reference teaches a method that promotes air inclusion and mechanical mixing of components, both of which the Tepic patent expressly seeks to avoid. Accordingly, the Tepic patent teaches away from making the combination that the Examiner advocates. As the Federal Circuit has stated, "There is no suggestion to combine, however, if a reference teaches away from its combination with another source". *Tec Air, Inc. v. Denso Manufacturing Michigan Inc.*, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999).

Since there is no motivation to combine the Tepic patent and the WO 97/18031 reference as the Examiner has done (and in fact the Tepic patent teaches away from such a combination), Applicant submits that pursuant to MPEP §2143, the Examiner has failed to establish a prima facie case of obviousness. Accordingly, Applicant submits that claims 1-11 and 17 are patentable over the Tepic patent and the WO

97/18031 reference.

The Examiner has rejected claim 13 under 35 U.S.C. §103(a) as being unpatentable over the Tepic patent in view of the WO 97/18031 reference, as applied to claim 1 above, and further in view of U.S. Patent No. 6,024,480 to Seaton et al. For at least the reasons set forth below, Applicant traverses this rejection.

The Seaton et al. patent discloses an apparatus 2 for mixing bone cement components. The apparatus 2 includes a housing 4 having a bone cement mixing chamber 5 containing a bone cement powder 7 and a mixing assembly 6. The mixing assembly 6 includes mixing paddles 92 secured to a rotatable shaft 94. A vial 10 containing monomer liquid 8 is disposed in a chamber 52 of an upper cover assembly 23 that is connected to the mixing chamber 5 by a port 88. A fine mesh glass fragment particle filter 182 is secured in the port. The monomer liquid 8 flows via gravity from the vial 10 into the mixing chamber 5 through the port 88. After the monomer liquid 8 is disposed in the mixing chamber 5, a vacuum is applied to the mixing chamber 5 and the chamber 52 to evacuate noxious fumes. The paddles 92 are then rotated to mix the powder 7 and the monomer liquid 8.

Since the Seaton et al. patent teaches adding the monomer liquid to the powder solely under the force of gravity and then mechanically mixing the powder and the liquid, it is clear that the Seaton et al. patent fails to show or suggest independent claim 1 and fails to cure the deficiencies of the primary reference, the Tepic patent, with regard to independent claim 1. Moreover, it is equally apparent that the Seaton et al. patent does not provide the motivation to combine the Tepic patent with the WO 97/18031 reference. Accordingly, Applicant submits that claim 1 (from which claim 13

depends) is patentable over the Tepic patent, the WO 97/18031 reference and the Seaton et al. patent. Since claim 13 depends from claim 1, Applicant considers it apparent that claim 13 is also patentable over the Tepic patent, the WO 97/18031 reference and the Seaton et al. patent. Moreover, Applicant submits that there is no motivation to combine the Seaton et al. patent with the Tepic patent since the ampule 12 in the Tepic patent is not disclosed as being composed of glass or being frangible. Thus, the motivation supplied by the Examiner simply does not exist.

The Examiner has rejected claims 18 and 19 under 35 U.S.C. §103(a) as being unpatentable over the Tepic patent in view of the WO 97/18031 reference, as applied to claim 1 above, and further in view of U.S. Patent No. 5,328,262 to Lidgren et al. For at least the reasons set forth below, Applicant traverses this rejection.

The Lidgren et al. patent discloses a method and apparatus for forming a bone cement mixture. Cement components are added to a mixing cylinder 3 so as to only partially fill the cylinder 3. Thereafter, a vacuum source 21 is connected to the mixing cylinder. While the vacuum source 21 applies a vacuum to the mixing cylinder 3, the cement components are mixed in the cylinder 3 by moving an operating rod 7 up and down in the mixing cylinder 3 so that the mixture passes through holes 10 in a mixing plate 8 attached to the rod 7. After the components are mixed, the bone cement mixture is collected at the top of the mixing cylinder 3 in a vacuum. The collection vacuum is disclosed as being at least 40% and preferably 80-95% percent vacuum.

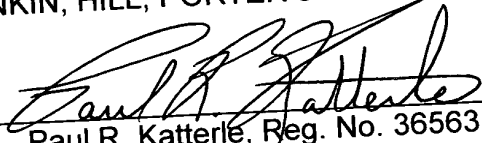
Since the Lidgren et al. patent teaches adding cement components together before applying a vacuum and then mechanically mixing the components, it is clear that the Lidgren et al. patent fails to show or suggest independent claim 1 and fails to cure the deficiencies of the primary reference, the Tepic patent, with regard to independent claim 1. Moreover, it is equally apparent that the Lidgren et al. patent does not provide the motivation to combine the Tepic patent with the WO 97/18031 reference. Accordingly, Applicant submits that claim 1 (from which claims 18 and 19 depend) is patentable over the Tepic patent, the WO 97/18031 reference and the Lidgren et al. patent. Since claims 18 and 19 depend from claim 1, Applicant considers it apparent that claims 18 and 19 are also patentable over the Tepic patent, the WO 97/18031 reference and the Lidgren et al. patent. Moreover, Applicant notes that the Lidgren et al. patent does not disclose what is ascribed to it by the Examiner. As set forth above, the 85-90% vacuum disclosed in the Lidgren et al. patent is not the mixing vacuum, as asserted by the Examiner. Rather, it is the *collection* vacuum.

In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge the same to our Deposit Account No. 18-0160, Order No. LUS-12520.

Respectfully submitted,

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